REMARKS:

Amendments to claims

Claim 1 has been amended to more clearly set out the present invention. More specifically, claim 1 has amended by incorporating the limitations of originally filed claim 13, thereby setting out that the present invention is concerned with a skin-mountable device in which a given hollow infusion needle can be replaced by a further hollow infusion connected to the same common fluid conduit.

In claims 1, 2, 6-8, 12, 15-17, 19 and 20 reference numerals have been deleted.

Claims 14 and 15 have been made dependent upon amended claim 1.

Claim 13 has been cancelled, the subject-matter having been incorporated in amended claim 1.

Amendments to drawings

The Examiner has objected to the drawings not showing the adhesive means (115, 215) specified in the claims.

Applicant acknowledges that the reference numerals 115 and 215 are missing in the drawings, thereby failing to identify the adhesive means. However, the adhesive means is shown in the drawings, only the reference numerals 115 and 215 have been omitted in the drawings by mistake.

Correspondingly, in amended figures 2, 4 and 7 reference numerals 115, 115 and 215 respectively have been added in drawing replacement sheets 1/6, 3/6 and 4/6 respectively. It is noticed that the embodiment of figure 7 belongs to Species II as identified by the Examiner in the Office Action dated August 1, 2006, however, as the applicant believes that the embodiment of figure 7 will be covered by an allowable generic claim, all three figures have been amended for the sake of completeness.

Basis for the amendments can be found in the specification page 14, lines 14-24, and page 18, lines 4-7.

Claim rejections – 35 USC 102

The examiner has rejected claims 1-7, 12-17, and 21 under 35 USC 102(e) as being anticipated by Aceti et al. US patent 7,004,928. .

Amended claim 1 defines (feature numerals added):

A needle device comprising:

(a) a mounting surface adapted for application to the skin of a subject,

(b) adhesive means arranged on the mounting surface for adhering the needle device to the skin of the subject,

(c) a plurality of needles, each needle comprising a distal pointed end adapted to penetrate the skin of the subject, and

(d) a common fluid conduit means,

(e) wherein a plurality of the needles are hollow having a distal and a proximal opening, the proximal opening being in fluid communication with the common fluid conduit means when the needle is in its second position, and

(f) wherein each needle has a first position in which the distal end is retracted relative to the mounting surface, and a second position in which the distal end projects from the mounting surface,

(g) the needles being arranged such that at least one needle can be moved from its first to its second position or from its second to its first position with at least one other needle not performing the same movement.

Having regard to Acebi et al., this document discloses a skin-mountable device which may be in the form of either (1) an analyte monitoring device, or (2) a drug delivery device (or a combination thereof). For both purposes the device comprises a plurality of micro-needles, each needle being associated with a micro-channel. In case the device is adapted to serve as an analyte monitoring device, each micro-channel serves to collect a sample when the needle is inserted. In case the device is adapted to serve as a drug delivery device, each micro-channel serves to hold an amount of a pharmaceutical agent, see e.g. column 9, lines 33-46. As follows from this arrangement, no central reservoir or common fluid conduit is provided. In contrast, each micro-

channel and its associated micro-channel serve as a dosing unit comprising a predetermined amount of an agent which can be emptied as a slider 268 moves over the compressible micro-channel, see column 11, lines 1-18.

Addressing original claim 13 the Examiner has indicated that reference numeral 234 denotes a common fluid conduit means, however, it appears that reference numeral 234 denotes a sensor mounted to the above-mentioned slider 268, see column 10, lines 61-67.

Consequently, Acebi et al. fails to disclose features (d) and (e) of amended claim 1.

Claim rejections - 35 USC 103

The examiner has rejected claims 1-8, 12 and 21 under 35 USC 103(a) as being unpatentable over Groth (WO 01/93927) in view of Aceti et al.

Groth discloses a needle magazine comprising a plurality of needles arranged in a shell, which magazine is adapted to be used in combination with a cartridge. Although the magazine is provided with a lower surface which allows it to be arranged on a skin surface during injection of an amount of drug, it is clear from the disclosure in Groth that the magazine is not intended for permanent placement on a skin surface but merely as a means for providing a cartridge with a new and sterile needle before each injection. Corresponding to the intended use, Groth discloses that the user will rotate the shell relative to the cartridge before and after use to position a needle relative to the cartridge, see page 3, lines 4-25.

Although it may be argued that it would also be possible to rotate the cartridge relative to the shell, it is clear from Groth that this is not the intended use of the disclosed magazine. Further, the provision of an adhesive on the lover surface of the magazine shell would prevent the magazine to be used in the way taught by Groth, thereby teaching away from such a modification.

Further, amended claim 1 now defines that the hollow needles can be arranged in fluid communication with a common fluid conduit when the needles are in their extended second position. Neither, Groth nor Aceti et al. disclose such a common conduit.

Further again, as the purpose of the magazine of Groth is to provide a number of needles each having a proximal end adapted to be inserted directly into the cartridge (see page 3, lines 9-14), it follows that a common conduit arranged between the proximal end of the needle and the cartridge would jeopardize the intended functionality of the disclosed magazine as it would prevent a fresh

needle to be inserted into the cartridge for each use of a new needle.

Turning to Aceti et al. as a starting point for the present invention, the question is whether it would be obvious to the skilled person to provide the needle device of Aceti et al. with a common conduit.

As also discussed above, Aceti et al. discloses a skin-mountable device which may be in the form of either an analyte monitoring device, or a drug delivery device, each comprising a number of needles which can be inserted one after the other. However, in the device of Aceti et al. each needle is provided as a functionally integrated part of either the analyte sensor means or the drug delivery means.

More specifically, when a micro-needle serves to collect an amount of an analyte, then the analyte is transferred to a micro-channel associated with that specific needle, the micro-channel serving as part of the sensor structures, see e.g. column 16 "Exemplary Sensor Structures" disclosing different sensor means. Correspondingly, when a micro-needle serves to deliver an amount of a drug the associated micro-channel also serves as a dosing means, each micro-channel holding an amount of drug, see e.g. column 11, lines 1-18.

There is no disclosure in Aceti et al. that the sensor means should be provided as a "central sensor unit" to which analyte is conducted via the individual micro-needles, the associated micro-channel and a common conduit connecting to such a central sensor unit. Correspondingly, there is no disclosure in Aceti et al. that the delivery and dosing means should be provided as a "central dosing and reservoir unit" from which medication is delivered via a common conduit connected to such a central reservoir unit, the individual micro-channels, and the associated micro-needles.

Apart from the technical teaching of Aceti et al., this reference as well as the other references on record, also fails to identify the problem addressed by the present invention. More specifically, the present invention addresses the problem of reducing the costs of operation of a skin-mountable device by prolonging the operational lifetime for such a device, see e.g. page 6, lines 25-33. This problem is solved by a needle device as defined in amended claim 1, such a device allowing a needle to be replaced with a fresh needle, the new needle still being connected to the same general structure, e.g. sensor or reservoir, via a common conduit.

In contrast and as discussed above, Groth provides a hand-held needle magazine allowing for easy replacement of a needle before injection from a cartridge, and Aceti et al. provides a needle device allowing a new micro-channel to be connected to a subcutaneous site for every insertion of a micro-needle.

Conclusion

In conclusion, Aceti et al. as well as Groth, alone or in view of any of the references on file, fail to make obvious to the skilled person a device or method as defined in amended claim 1.

All further claims are dependent upon an independent claim.

In view of the above, applicants respectfully submit that all claims are in condition for allowance.

The Commissioner is hereby authorized to charge any fees, including fees for extensions of time, in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. Should the Examiner have any questions or concerns, she should feel free to contact the applicants' attorney to discuss them.

Respectfully submitted,

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